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February 24, 2004

OVERNIGHT COURIER 02/24/04

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Amendment to Citizen Petition
Docket Number 2002P-0297/CP1
Amendment for Inclusion of Pediatric Waiver Request

Dear Sir or Madam:

The petition cited above was originally submitted on June 28, 2002. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug product, Propoxyphene Hydrochloride, Acetaminophen and Caffeine Capsules 65 mg/389 mg/32.4 mg, is suitable for submission in an abbreviated new drug application. The petition was **approved** on February 13, 2003. On February 3, 2004, we received a letter from the Office of Generic Drugs stating that the approval of the suitability petition has been **suspended**.

The Agency referenced the provisions of the Pediatric Research Equity Act (PREA) of 2003, which amended the Federal Food, Drug and Cosmetic Act, to provide the Agency authority to require drug firms to study certain drugs in pediatric patients if the Agency felt that such study would provide beneficial health data for that patient population. Please be advised that **the petition as originally submitted contained a request for waiver based on the then relevant Pediatric Final Rule (21 CFR 314.55(c)(2)(i))**. However, because the Agency reviewed the petition and approved it after the Pediatric Final Rule was invalidated on October 17, 2002, the Agency was not required to and did not review that request. The Agency apparently overlooked the fact that the petition, as originally submitted, already contained a pediatric waiver request that could have been evaluated in the context of the PREA, and instead, acted to suspend the approval of the petition without a review of the original and still pertinent waiver request. In that regard please consider this amendment to the petition requesting such a waiver.

The act provides a provision for a waiver from such requirement if:

> (iii) the drug or biological product;
>
> (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
>
> (II) is not likely to be used in a substantial number of pediatric patients.

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The petitioner hereby requests that a waiver from the conduct of pediatric patient be granted for the reinstatement of approval of this petition to permit subsequent ANDA filing.

The basis for this request is that the newly proposed combination product will not offer a meaningful therapeutic benefit over existing treatments for pediatric patients and the new product is not expected to be utilized in a significant number of pediatric patients. There are numerous approved products, many in dosage forms more appropriate for use in treating pain in pediatric patients (e.g., acetaminophen with codeine solution and hydrocodone bitartrate and acetaminophen elixir where approved dosing recommendations down to 2 years of age are provided). It is not anticipated that the simple substitution of an equipotent dose of acetaminophen for aspirin in the existing combination product will likely promote the use of the product in pediatric patients. In addition, this product will, by nature of its composition, be of a relatively large capsule size (greater than 500 mg) and would contain a dose of 389 mg of acetaminophen. Both of these factors would not appear to be particularly useful in treating pediatric patients especially with other more convenient (liquid) dosage form products available in the marketplace.

Based on the use and nature of the RLD and the proposed product, the change in active ingredient to include an equipotent dose of acetaminophen substituted for aspirin would not likely change the use of the product or make it any more likely to be used in pediatric patients.

For the reasons stated above and consistent with the provisions of the Pediatric Research Equity Act of 2003, the petitioner respectfully requests that this waiver be granted. Due to the fact that this ANDA suitability petition as originally submitted contained a pediatric waiver request and the Agency chose to ignore that request when making a determination to suspend its approval, the undersigned requests that the review of this waiver request be conducted in an expedited manner.

Sincerely,

Robert Pollack /jf

Robert W. Pollock
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RWP/jf

cc: Emily Thomas (Office of Generic Drugs)
Martin Shimer (Office of Generic Drugs)

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